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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,907

05/16/2005

Thomas Hogberg

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02/14/2008

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,907	Applicant(s) HOGBERG ET AL.	
	Examiner SUN JAE Y. LOEWE	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,11-19 and 45-54 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

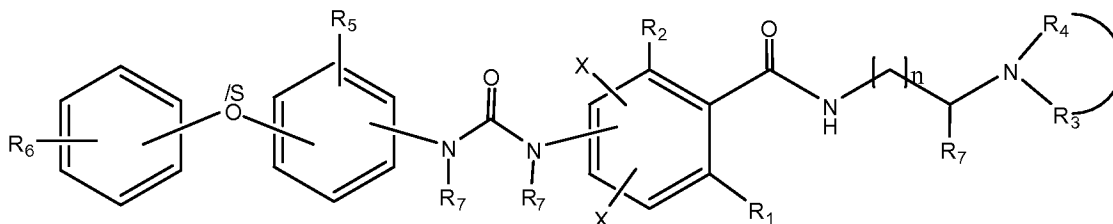
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-19 and 45-54 are pending in the instant application. Claims 20-35 and 55 were cancelled by preliminary amendment filed on October 8, 2004. Claims 36-44 were cancelled by amendment filed on December 12, 2007.

Election/Restrictions

2. The scope of the examined subject matter is: compounds of Formula I which meet the structural limitations defined by



Note: This scope was set forth in the previous office action (see page 6). However, due to a typographical error, two of the nodes associated with variable Q were transcribed incorrectly. It is herein clarified that the correct scope of examination is given by the generic formula above.

3. Sections 2 and 10 of the office action dated June 12, 2007 set forth different scopes of examination. The correct scope is that denoted on section 10 of the office action dated June 12, 2007 (with the correction discussed above). The scope set forth in Section 2 of the office action dated June 12, 2007 was in error. This clarification/correction does not affect the grounds of rejection previously made. However, claims which are drawn to non-elected, non-examined subject matter were inadvertently not withdrawn. These claims are withdrawn herein (see below, Section 4).

4. Compounds of Formula I which are outside of the scope denoted by the generic structure above are withdrawn from further consideration. Claims 2, 3, 9 and 10, being drawn to these non-elected compounds, are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Response to Amendment

5. Applicant's amendment to the claims has been fully considered. The following grounds of objection/rejection (office action dated June 12, 2007) are withdrawn as a result of the amendment: section 6 (objection to specification), section 8 (claim objection), section 9 (claim objection), sections 11 - 13 (35 USC 112 2nd rejections).

Response to Arguments

6. Applicant's arguments have been fully considered, however, they are not persuasive in overcoming 35 USC 112 1st paragraph rejections (sections 10 and 12). Therefore, the rejections are maintained and hereby made FINAL. See response to arguments below:

- a) “The scope of the claims with respect to R³ and R⁴ is congruent with the scope of the disclosure for the species disclosed in the specification.”
“The inventors also demonstrated 187 examples.”
“An actual reduction to practice
is not necessary as long as the written description enables one of ordinary skill in the art to make and use the invention without undue experimentation.”
- A prima facie case of lack of written description was made based on the insufficiency of the disclosure of actual species to support the claimed genus. The actual species described represent compounds wherein R3 and R4 join together to form piperidine, piperazine, pyrrolidine or morpholine. The genus encompasses compounds wherein R3 and R4 join together to form “a heterocyclic ring further comprising oxygen or nitrogen atoms.” Based on the definition of heterocycle provided by the specification (pg. 3), the claims encompass compounds wherein R3 and R4 join to form, for example: tetrahydrofuran, furan, tetrahydrothiophene, thiophene, pyrroline, pyrrole, dioxolane, pyrazolidine, imidazolidine, pyrazole, diazole, triazole, isoxazole, oxazole, thiazole, isothiazole, azepine, oxepin, thiopin, benzofuran, indole, indazole, quinoline, etc. The genus of compounds claimed are structurally diverse; one of ordinary skill could not predict the results

Art Unit: 1626

(ie. inhibition of MCH receptor) obtained from these species. The evidence presented in the previous office action (pg. 7 and 9) indicates that one of ordinary skill could not predict the operability in the invention of any species other than those disclosed. Applicant's attentions is respectfully directed to MPEP 2163.II.A.3.(a).(ii). These guidelines were applied in the determination of prima facie lack of written description.

- b) “One of skill in the art would be able to easily and without undue experimentation utilize the disclosure and examples to assess the activity of further compounds that fall in the same genus as those disclosed.”

The specification teaches how to use compounds wherein R3 and R4 join to form piperidine, piperazine, pyrrolidine or morpholine. The specification does not teach how to use compounds wherein R3 and R4 join to form any other ring system encompassed by the definition of “a heterocyclic ring further comprising oxygen or nitrogen atoms.” Based on the analysis of the Wands factors, it has been determined that the amount of experimentation needed to practice the invention commensurate in scope with the claims is undue. See office action section 12. Applicant's attention is further directed to MPEP 2164.03, which contents were assessed in determining that the claims prima facie lack enablement for the full scope claimed.

- c) “The specification discloses “[t]he invention also related to solvates, and prodrugs of the compounds of the invention”
- “The specification discloses that “[t]he invention encompasses a compound in amorphous, any polymorphous or any crystalline form.”
- “One of skill in the art at the time the invention would be familiar with how to make and use crystalline/amorphous/solvated forms of compounds. ”
- “One of skill in the art would, based on the extensive disclosure of this application ... be capable of making and using crystalline/amorphous/solvated forms ... without undue experimentation.”

There is no specific teaching on how to make/use solid forms (including solvates) or prodrugs. The teaching is generic, and limited to what Applicant has quoted in the remarks: ie. see excerpts above. Based on similar reasoning as presented above, it is maintained that the claims prima facie lack written description and enablement. As previously discussed (see pg. 9-10 of office action dated June 12, 2007), this determination is based on the low level of predictability and the lack of a specific teaching (eg. reduction to practice) for the claimed invention.

7. Applicant has not specifically traversed the 35 USC 112 2nd paragraph rejection set forth in section 14 of the office action dated June 12, 2007. This ground of rejection is maintained and hereby made FINAL.

Claim Objections

8. Claims 1, 4-8, 11-19 and 45-54 objected to for containing non-elected subject matter.

9. Claim 53 objected to because of the following informality. Based on the dependency to claim 46, the claim is interpreted to comprise a compound according to claim 1. The reference to plural claims, ie “~~according to claims~~”, is confusing. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 1 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim has been amended to recite the structural limitation:

“~~partially or fully fluorinated alkoxo or partially or fully fluorinated thioalkoxy groups.~~” This limitation does not appear to be supported by the originally filed specification.

Allowable Subject Matter

11. The subject matter denoted by the subgenus of 2 appears to be allowable over the prior art.

Conclusion

12. No claims allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.